JUL 2 0 2012

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510(k) SUMMARY

(As Required per 21 CFR 807.92(c))

GENERAL INFORMATION:

510k Owner's Name	Bovie Medical Corporation
Address	5115 Ulmerton Road Clearwater, Florida 33760-4004
Telephone Number:	(727) 384-2323
FAX Number:	(727) 322-4465
Contact Person	Richard A. Kozloff Vice-President; Quality Assurance/Regulatory Affairs
Date Prepared:	May 9, 2012

DEVICE DESCRIPTION:

Trade Name:	Bovie® Cautery Device
Common Name:	Battery Operated Cautery; Cauterizer
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification:	21CFR 878.4400; Class II; Product Code GEI
Legally Marketed Predicate Device(s):	**Various Hand Held, Battery Operated Cautery Devices** (K945757, K945765, K945492, K945764, K810909, K810017, K945760, K945759, K945493, K945762, K945763)

5115 Ulmerton Road • Clearwater, FL 33760-4004 • Phone: 727-384-2323 • Fax: 727-347-9144 • www.boviemed.com

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(As Required per 21 CFR 807.92(c))

DEVICE FUNCTION, TECHNOLOGY, AND INTENDED USE:

Bovie® Cauteries are single use, battery operated devices. The device is activated by pressing the green button on the cautery body and is deactivated by releasing the button (in the default position, the cautery does not operate). Once the button is pressed, an internal circuit is completed that directs power from an internal battery to the cautery tip which in turn heats. The heated tip is introduced to the surgical site and the heat vaporizes the water component in blood/tissue, causing a clot that halts the bleeding.

Cautery device technology remains mostly unchanged from those manufactured and sold over the last 30 years. These devices incorporate one or two 1.5 volt batteries as a power source and an internal conductor strip to direct power to the tip. **The devices that are the subject of this submission have been designed with additional safety enhancements, including a recessed activation button (to prevent inadvertent activation if the device is placed on a surface without the protective cap in place) and easily removable batteries that prevents activation of the device after its disposal.** The batteries may also be recycled rather than discarded in the user facility biohazard waste stream. Safety enhancements were made to prevent inadvertent device activation in the event that the user does not comply with the recommended disposal instructions after use.

Apart from the added safety features, these cautery devices remain mostly unchanged from those previously cleared. The patient contacting tip component and the cautery handle materials remain the same. Cautery tip configurations (shapes) are also unchanged from those previously cleared. A change to improve manufacturability was made to eliminate the cautery head component and to install cautery tip tubes directly into the cautery handle. The previous cautery head design was not patient contacting. Warnings and Cautionary labeling are carried through to the new design. Device packaging is also unchanged.

INTENDED USE:

Bovie® Cautery Devices are used for stopping small bleeders in hemostasis and other similar uses.

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510(k) SUMMARY

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(As Required per 21 CFR 807.92(c))

Characteristics	Bovie® Cauteries (This Submission)	Battery Operated Cauteries (Various Submissions)
Indications for Use	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis and other similar uses.	Used for stopping small bleeders in hemostasis and other similar uses.
Disposal Instructions	Cut tip or remove tip using hemostats. Replace the cover cap to prevent button activation. Twist the battery compartment to remove and separate batteries.	Cut tip or remove tip using hemostats. Replace the cover cap to prevent button activation.
Sterility	Single Use; Sterilized by Ethylene Oxide; Sterility Assurance Level of 10^{-6}.	Single Use; Sterilized by Ethylene Oxide; Sterility Assurance Level of 10^{-6}.
Design for Safety	Easily removal battery pack and recessed activation button.	Non-removable batteries and non-recessed activation button.
Materials	Patient contacting tips constructed of Nichrome 80 and Kanthal A-1. Cautery handles constructed of Acrylonitrile Butadiene Styrene (ABS). Cautery tip tubes are embedded in the handle.	Patient contacting tips constructed of Nichrome 80 and Kanthal A-1. Cautery handles constructed of Acrylonitrile Butadiene Styrene (ABS). Cautery tip tubes are embedded in a Delrin® cautery head that is placed into the handle.
Energy Source	Device is powered by one or two 1.5 volt alkaline batteries.	Device is powered by one or two 1.5 volt alkaline batteries.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bovie Medical Corporation
% Mr. Richard Kozloff
Vice President, Quality Assurance/Regulatory Affairs
5115 Ulmerton Road
Clearwater, Florida 33760

JUL 20 2012

Re: K121441
Trade/Device Name: Bovie® Cautery Device
Regulation Number: 21 CFR 886.4115
Regulation Name: Thermal cautery unit
Regulatory Class: Class II
Product Code: HQP
Dated: July 05, 2012
Received: July 06, 2012

Dear Mr. Kozloff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121441

Device Name: **Bovie® Cautery Device**

Indications for Use:

Bovie® Cautery Devices are used for stopping small bleeders in hemostasis and other similar uses.

Neil R P Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121441

Prescription Use ✓ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)